

Appl. No. : 09/782,534  
Filed : February 13, 2001

### REMARKS

Claims 6, 8-11, 15-17, 19, 21, 23, 24, 26, 27, 32, and 45-47 were previously cancelled, without prejudice. In the Office Action mailed August 23, 2004, the Examiner withdrew from consideration Claims 7, 12-14, 18, 20, 22, 25, 28-31, 33-44, and 50-52. In the April 20, 2005 Office Action the Examiner acknowledged that Claim 1 has been amended but maintained rejections of Claims 1-5, 48, and 49. In response to the April 20, 2005 Office Action and to facilitate examination of the present application, Applicants cancelled Claims 7, 18, 20, 22, 25 and 28, without prejudice and retaining the option to reintroduce these claims at a later time. Claims 1-5, 48, and 49 are the only claims pending in the present application. In the Office Action dated November 9, 2005, the Examiner maintained rejections of Claims 1-5, 48, and 49. Applicants responded in an Amendment filed April 4, 2006, and a personal interview was conducted on April 10, 2006 among Examiners Bennett and Ali, and the undersigned.

#### Claim Rejections - 35 U.S.C. § 103

Applicants respectfully traverse these rejections and contend that the Examiner has failed to establish a *prima facie* case of obviousness. In order to establish a *prima facie* case of obviousness, the Examiner must show:

- (i) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings,
- (ii) a reasonable expectation of success, and
- (iii) the prior art reference or references combined teach or suggest all the claim limitations. (See MPEP § 2142)

Applicants do not believe that Reiley and McFarlane suggest or motivate one of ordinary skill in the art to modify either reference or combine them to obtain Applicants' claimed invention.

Nonetheless, Applicants have amended the claims herein to approach the invention from a different perspective, which distinguishes over the cited art.

In particular, Reiley et al. fails to disclose or suggest an assembly including an elongated discectomy instrument which is axially moveable within a discectomy sheath, which is in turn axially moveable within an anterior tract sheath. The discectomy instrument has a cutting head

Appl. No. : 09/782,534  
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which is movable between a laterally extending orientation when unconstrained by the discectomy sheath, and an axial orientation when constrained by the sheath.

Although the embodiments of Figures 12, 13 and 14 in Reiley appear to disclose a blade having a laterally extending orientation, Reiley contains no disclosure of reverting that blade to an axial orientation by retraction into a discectomy sheath. To the contrary, referring to Figures 15 and 16, the guide sheath 124 in Reiley appears to have a sufficient inside diameter to accommodate the cutting blade 110 without changing it from its lateral orientation.

Moreover, Applicants have amended Claim 1 herein to further recite that the cutting head is biased laterally against an interior surface of the discectomy sheath, to move the cutting head from the axial orientation when inside of the sheath to the laterally extending orientation when unconstrained by the sheath. One species of this invention is illustrated, for example, in Figures 53 and 54 of Applicants' instant specification. The blades 348 and 349 illustrated in Figure 53 are positioned within discectomy sheath 180, in an axial orientation. When the blades 348 and 349 are no longer constrained by the discectomy sheath 180, the cutting head moves from the axial orientation to a laterally extending orientation as illustrated in Figure 54. See, for example, paragraph 151 in Applicants' publication number US 2003/0191474 A1:

Figures 53-55 depict a further discectomy instrument 340 comprising an elongated drive shaft 344 with a distal cutting head 342 comprising a pair of blades 348 and 349 attached to the shaft distal end 346 and that extend laterally when unrestrained as shown in Figures 54-55 but can be bent or folded against the discectomy sheath wall when restrained in the discectomy sheath lumen as shown in Figure 53.

Applicants respectfully submit that this presently claimed structure is nowhere disclosed or suggested in Reiley. For example, Figure 1 in Reiley discloses a filament loop 22 which may be formed at the distal end of a catheter tube 12 by distally advancing a slide controller 30 to advance the filament.

Applicants respectfully submit that the filament 22 cannot properly be considered a cutting head as presently claimed. In addition, Applicants respectfully submit that Reiley fails to disclose a separate discectomy sheath which is distinct from an anterior tract sheath as presently claimed. Referring to Figure 4 of Reiley, the catheter tube 12 may be axially moveable within a

Appl. No. : 09/782,534  
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guide sheath 34. Thus Reiley fails to disclose an assembly which additionally includes an anterior tract sheath having a distal end for engaging an anterior surface of the sacral vertebral body. Reiley's conventional lateral approach to the spine (see, e.g. Figure 25 in Reiley) requires the use of an external guide sheath 34 to provide access to the vertebral body within which the procedure is to be performed. The catheter tube 12 is advanced through the guide sheath 34 and the filament 22 may be thereafter deployed at the working site. Reiley contains no suggestion for the addition of an additional anterior tract sheath as claimed by Applicants.

Applicants' claimed cutting assembly is instead necessitated by Applicants' unique access pathway to the spine. Referring, for example, to Figure 9 of the present application, an anterior tract sheath 96 is provided for reaching from the dermal surface to an anterior surface of the sacral vertebrae. The discectomy instrument discussed in connection with Figures 53 through 55 is thereafter advanced through the anterior tract sheath 96. The biased cutting head remains within the discectomy sheath while the distal end of the discectomy sheath is placed within or adjacent a vertebral body within which the procedure is to be accomplished. That vertebral body is different than the vertebral body against which the anterior tract sheath 96 is positioned. Thus, the biased discectomy head is restrained by the discectomy sheath to allow the axial advance of the cutting head for a distance beyond the end of the anterior tract sheath 96 before the cutting head is allowed to move from the axial orientation to the laterally extending orientation by removing the constraint of the discectomy sheath. This relationship is unnecessary in the context of Reiley, and only necessitated by Applicants' novel methodology. Thus, Applicants respectfully submit that the prior art contains no motivation to modify the Reiley assembly to produce Applicants' presently claimed invention.

The embodiments of Figures 12 through 21 in Reiley were also discussed at the interview. In these embodiments, a cutting blade 110 or 78 appears to reside in a laterally extending orientation. However, the cutting blades 110 and 78 are not configured to cooperate with a guide sheath (e.g. guide sheath 124 in Figure 15) such that the cutting head is biased laterally against an interior surface of the sheath to move the cutting head from an axial orientation to a laterally extending orientation when unconstrained by the sheath as presently claimed.

Appl. No. : 09/782,534  
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To the contrary, the guide sheath 124 is illustrated as having a sufficient inside diameter to accommodate the cutting blade 110 without reconfiguring the cutting blade 110 into an axial orientation. See, e.g., Reiley at Column 7 lines 35 through 60.

Accordingly, Applicants respectfully submit that Reiley fails to disclose or suggest a cutting assembly which includes a discectomy sheath, an anterior tract sheath, and a cutting head which is biased laterally against an interior surface of the sheath to move the cutting head from the axial orientation to the laterally extending orientation when unconstrained by the sheath. Given the clinical use of the device disclosed in Reiley, and functional requirements imposed thereby, persons skilled in the art would have no motivation to modify the system disclosed in Reiley to produce Applicants' present claimed invention.

In view of the foregoing, Applicants respectfully submit that Claim 1 is neither disclosed or suggested by Reiley, and McFarlane fails to suggest modifying Reiley in a manner that would fall within the scope of Applicants' claimed invention.

Claims 2-5, 48, and 49, which depend from Claim 1, are believed to be patentable for the reasons stated above with respect to Claim 1. Applicants respectfully submit that Claims 1-5, 48, and 49 would not have been obvious under 35 U.S.C. § 103(a) and are patentable over Reiley et al. in light of McFarlane. Accordingly, Applicants respectfully request that the rejection of Claims 1-5, 48, and 49 be withdrawn.

In view of the foregoing, Applicants respectfully submit that the pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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